

ICH M10 EWG Work Plan

February 05, 2022

Topic Adoption date: *June 2016*

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Regulatory Chair: *Dr. Brian Booth – FDA, United States*

Last Face-to-Face Meeting: *Singapore, Nov 2019*

1. Key milestones

1.a. Current status of key milestones

Past completion date	Milestone
<i>Oct. 2016</i>	<i>Concept Paper endorsement</i>
<i>Oct. 2016</i>	<i>Business Plan endorsement</i>
<i>Jan. 23, 2019</i>	<i>Step1 sign-off</i>
<i>Feb. 26, 2019</i>	<i>Step 2b endorsement</i>
<i>Mar - Sept, 2019</i>	<i>Step 3 public consultation</i>

1.b. Future anticipated key milestones

Expected future completion date	Milestone
<i>May 2022</i>	<i>Face-to-Face meeting (Athens)</i> <i>Revision of the guideline text for finalisation by reflecting the public consultation comments</i> <i>Preparation of the draft training materials</i> <i>Step 3 sign-off and Step 4 adoption</i>
<i>Nov 2022</i>	<i>Finalising the training materials</i>

2. Timeline for specific tasks

Beginning date	End date	Task / Activity	Details
Feb. 2022	<i>Feb. 2022</i>	<i>Email/Teleconferences</i>	<i>Revision of guideline text, Regulatory review (All sections) Training material preparation (All sections)</i>
Mar. 2022	<i>Mar. 2022</i>	<i>Email/Teleconferences</i>	<i>Revision of guideline text, EWG review (All sections) Training material, Regulatory review (All sections)</i>
Apr. 2022	<i>Apr. 2022</i>	<i>Teleconferences</i>	<i>Training material, EWG review (All sections)</i>
May. 2022	<i>May. 2022</i>	<i>Face-to-face meeting (Athens)</i>	<i>Review of guideline text Review of training material</i>